Quality Assessment Criteria

831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

The scope of this RfP contains the following BBB's / categories: Data Acquisition & Processing, Patient Engagement, Setup & Design, Closeout & Reporting, Operation & Coordination, and Recruit & Enroll.
For all these BBB's, quality criteria are defined, including some generic criteria that are applicable to all BBB's.

Generic criteria:

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
1	Technology/system is compliant with applicable privacy and safety standards and regulations, such as FDA, GDPR, MDR, ISO.	NA	NA	NA	1
2	Technology allows multiple simultaneous accesses and edits from multiple locations (web/cloud-based access)	NA	NA	NA	1
3	Technology has strong password requirements (e.g. two-factor authentication, does not allow to save password on device).	NA	NA	NA	1
4	Unauthorized log-in attempts are limited and recorded	NA	NA	NA	1
5	Technology enables automatic log-off for long, idle periods (e.g. at least 15 minutes)	NA	NA	NA	1
6	Technology enables protection of records to enable their accurate and ready retrieval throughout the records retention period	NA	NA	NA	1
7	Technology enables restriction of user access to data with different levels of access permission	NA	NA	NA	1
8	Technology systematically considered human factors in the development of the device user interface (such as task/function analyses, user studies, prototype tests and mock-up reviews)	NA	NA	NA	1
9	The technology production units are tested under actual or simulated use conditions	NA	NA	NA	1
10	The system interface is at least in the local language (of the specific country, and approved by EC) and in English.	NA	NA	NA	1
11	Technology (visual information, language, design) is appropriate for the target audience	NA	NA	NA	1
12	Technology should allow participants to select preferred way of communication (phone, email etc.)	NA	NA	NA	1
13	Technology has adequate hardware quality: inconspicuous, small and noise-less, sufficient battery life (on full charge), charging time is short, includes country-specific electrical fittings/voltages, water resistant technology.	NA	NA	NA	1
14	Technology provider has a business continuity plan	NA	NA	NA	1
15	Technology manufacturer provides sufficient (e-)training tools such as user manual or instructional videos for the technology users	NA	NA	NA	1
16	Technology updates are seemless (without interruption of functionalities)	NA	NA	NA	1
17	Technology vendor maintains operational services related to tech equipment: a tracking system of distribution of the product, from which reports can be pulled by users/sponsor; delivery of devices to patients; replacement of defective devices	NA	NA	NA	0,5

BBB: Set up & design

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
18	Technology is able to share documents with potential sites to analyze site feasibility	Operational Feasibility Assessment and Selection	Site Feasibility Documentation Database		1
19	Technology is able to perform and track online Investigator/Site Staff Training	Site start-up			1
20	Technology is able to track pre study visits	Site start-up	Study Start-up Data Repository		0,5
21	Technology enables automated site/patient payments	Study Payments Management	Study Reimbursement & Payments System		0,5

BBB: Rectruitment & enrollment

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
22	Information materials given during informant consent process are accessible to participants.	Obtaining informed consent	Participant education		1
23	Technology allows PI oversight with regards to coordination and management of the informed consent procedure	Obtaining informed consent	Documentation management		1
24	Participant has access to the informed consent application and his/her signed consent form (not only members of the research team)	Obtaining informed consent			1
25	Technology verifies the authenticity of the informed consent document	Obtaining informed consent	Clinical monitoring		1
26	Technology allows the investigator to contact the participant directly	Obtaining informed consent	Patient-HCP interaction and communication		1
27	Technology allows the participant to contact the investigator directly	Obtaining informed consent	Patient-HCP interaction and communication		1
28	Technology saves information during the process (not only after completing steps)	Obtaining informed consent	Management of study-generated data		0,5
29	Technology allows adequate access for external monitors to check the informed consent procedure	Obtaining informed consent	Clinical monitoring		1
30	Technology evaluates/tracks metrics (i.e. time-of-use schedule, approval deadlines, number of findings during monitoring, revocation rate)	Obtaining informed consent	Performance Monitoring		0,5
31	Technology allows participant to choose the format/media for receiving a copy of the signed consent form	Obtaining informed consent			0,5
32	Technology has the possibility of signing with electronic signature	Obtaining informed consent	System approval facilitation		1
33	Technology has an official certificate for signing with electronic signature	Obtaining informed consent	System approval facilitation		1
34	Technology is adapted to use by low literate participants	Obtaining informed consent	Creation of ICF	Participant education	1
35	Technology is adapted/adaptable to use by participants with special needs (i.e. vision problems)	Obtaining informed consent	Creation of ICF	Patient technology enablement	1
36	Technology allows investigator/participant to change language	Obtaining informed consent	Creation of ICF	Patient technology enablement	1
37	Technology offers the possibility of re-consent after amendments to the protocol	Obtaining informed consent	Documentation management		1
38	In case of amendments and re-consent, the technology highlights relevant changes for participants for quick and easy identification of changes	Obtaining informed consent	Creation of ICF		1
39	Technology includes validated methods to verify inclusion and exclusion criteria of a subject for trial participation	Screening			1
40	The enrollment data allow for daily visualization of enrollment statistics such as eligibility and enrollment rates, stratified numbers and proportions	Performance monitoring			1
41	Steps from eligibility to enrollment for each subject are recorded in such a way that none of the eligible subjects (enrolled and not-enrolled) is lost in the data registration	Management of study-generated data			1
42	Technology includes a portal or landing page with outreach to patients via social media, technology platform	Participant outreach	Participant outreach	Pre-screening	1
43	Technology is able to setup recruitment plan based on add-on variables during the study (e.g. high percentage of non-recruiting sites; high drop out rate)	Pre-screening	Pre-screening	Management of study-generated data	0,5

BBB: Data acquisition & processing

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
44	Technology is able to classify each data point (participant identification, endpoint or safety-related data)	Management of study-generated data			1
45	Technology allows integration of third party generated or maintained critical data (e.g. central laboratories, electronic health records, ePROs) to be integrated into the database	Management of study-generated data	eCRF and system query design		1
46	Technology safeguards that recording of a clinical observation is made at the same time as when the observation occurred or after it occurred (data entry for future not allowed). If real-time recording is not possible, the chronology of events is recorded, with pre-defined maximum delay	Clinical data repository management	Gathering and management of real-life data		1
47	Technology safeguards records to be retained and maintained for a period of time specified in the country-specific overseeing authorities and regulations (e.g. EMA; GCP)	Data reconcilliation & Query management	Gathering and management of real-life data		1
48	Technology safeguards records are available for country-specific regulatory inspections during the study	Data reconcilliation & Query management	Gathering and management of real-life data		1
49	Technology safeguards records are independently preserved at clinical site and/or some other designated site (e.g. technology provider)	Management of study-generated data	Data reconcilliation & Query management		1

50	Technology safeguards data generated is easily accessible for retrieval throughout the records retention period	Management of study-generated data	Data reconcilliation & Query management		0,5
51	Technology that needs calibration has calibration procedures in place to document when potential calibration errors are identified and how the calibration issue was resolved	Gathering and management of real-life data			1
52	Validation of data collection/measurements has been done in a controlled environment (the laboratory or clinic) and a real-world environment	Gathering and management of real-life data			1
53	If algorithms are used, the process by which the algorithm was developed is published or otherwise made freely available	Management of study-generated data	Gathering and management of real-life data	Clinical data repository management	0,5
54	The technology includes a system to collect and preserve clinical data which is pre-managed and validated according to SOP (Standard Operation Procedures)	Clinical data repository management	Gathering and management of real-life data		1
55	The technology is able to discern invalid or altered records	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	1
56	Technology generates electronic data that meets the same or better data quality and integrity as traditional/paper records	Data transformation & standardization	Data analysis		1
57	Technology allows collection of sufficient contextual information to understand the outcome data captured by mobile technologies while avoiding the collection of intrusive data	Gathering and management of real-life data	Data transformation & standardization		1
58	Technology allows collection of metadata indicating source of the data and a UTC time stamp	Clinical data repository management	Gathering and management of real-life data		1
59	Technology safeguards data monitoring occurs in an automated, centralized fashion so that discovery of irregular data calibration errors, can be flagged and investigated	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	1
60	Technology uses Electronic Prompts, Flags, and Data Quality Checks in the eCRF	Data transformation & standardization	Data analysis		1
61	Technology provides the possibility for clinical investigator to review and electronically sign the completed eCRF for each subject	eCRF and system query design	Gathering and management of real-life data		1
62	Technology provides the possibility for clinical investigator to be masked to specific data in the eCRF	eCRF and system query design	Management of study-generated data		0,5
63	Technology allows automated de-duplication, filtering, and parsing of data	Data reconcilliation & Query management	eCRF and system query design	Data transformation & standardization	1
64	Technology ensures that quality of data captured by mobile technologies is monitored centrally through automated processes	Clinical data repository management	Gathering and management of real-life data	eCRF and system query design	1
65	Technology automatically transfers individual participant data to a central server or other data gathering platform for the trial	Gathering and management of real-life data	Clinical data repository management		1
66	Technology includes a data transfer plan that specifically guides how data from participant, to data warehouse, to data monitoring and programming, to archiving must flow	Data reconcilliation & Query management	Clinical data repository management		1
67	Technology allows to demonstrate that the data have not been corrupted following creation	Gathering and management of real-life data	Management of study-generated data		1
68	Technology safeguards presence of data element identifiers	Data transformation & standardization	Clinical data repository management	Gathering and management of real-life data	0,5
69	Technology ensures secure, computer-generated, time-stamped, electronic audit trails of users' actions and changes to data	Data transformation & standardization	Management of study-generated data	Clinical data repository management	1
70	Technology ensures audit trails can not be overridden	Data transformation & standardization	Management of study-generated data	Database lock	1
71	Data elements are in line with clinical interchange standards such as CDISC (Clinical Data Interchange Standards Consortium)	Data transformation & standardization	Management of study-generated data		1
72	Technology restricts users' access to data so they cannot tamper with them	Management of study-generated data	Clinical data repository management	Data reconcilliation & Query management	1
73	Technology has includes a robust, risk-based data security system	Data transformation & standardization	Management of study-generated data	Data reconcilliation & Query management	1
74	Technology has limited amount of data stored on a mobile device	Clinical data repository management	Gathering and management of real-life data	Management of study-generated data	0,5
75	Technology includes "Certificate Pinning" software on the mobile technology and on the server (Internet security mechanism which allows websites to resist impersonation by attackers using misissued or otherwise fraudulent digital certificates)	Clinical data repository management	Gathering and management of real-life data	Management of study-generated data	0,5
76	Technology has data security measures in place such as data encryption, checksums and tokenization in place	Data transformation & standardization	Data reconcilliation & Query management	Management of study-generated data	1

77	Technology includes services such as backups and disaster recovery arrangements in service level agreements with outsourced electronic service vendors	Management of study-generated data	Clinical data repository management	Data reconcilliation & Query management	1
78	Devices into or onto which data are stored are "scrubbed" at a proscribed time interval by the app/programmer.	Data reconcilliation & Query management	Clinical data repository management	Gathering and management of real-life data	1
79	Technology uses a secure network encryption certificate, such as Secure Sockets Layer (SSL) or Transport Layer Security (TLS), and transmit data wirelessly over Hypertext Transfer	Data reconcilliation & Query management	eCRF and system query design		1
80	Technology uses a protocol Secure (HTTPS), or similar secure file transfer protocol such as SFTP (Secure File Transfer Protocol)	Data reconcilliation & Query management	eCRF and system query design		1
81	Technology includes firmware that maintains data equivalence	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	0,5
82	Firmware that ensures data security is optimized	Management of study-generated data	Gathering and management of real-life data	eCRF and system query design	1

BBB: Operations & Coordination

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
106	Technology allows managing the timeline of study (e.g. regulatory complete)	Study oversight	Regulatory Management	Performance monitoring	1
107	Technology allows managing clinical trial contract information (contract timeline, stakeholders, negotiations, etc.)	Study oversight	Documentation management	Inspection facilitation	1
108	Technology allows managing all documents generated during clinical trials, separated by department	Documentation management	Clinical monitoring	Inspection facilitation	1
109	Technology allows identifying a protocol deviation/violation	Manage Protocol and GCP deviations	Safety Management	Inspection facilitation	1
110	Technology allows managing communication with a site or other organization	Vendor management (if other organization are vendors)	Study oversight		0,5
111	Technology allows managing information about interventional product, vendor or sponsor	Vendor management	Study oversight		0,5
112	Technology allow tracking and reporting of Green Light Approvals/Site Activations	Regulatory Management	Performance monitoring	Clinical monitoring	1
113	Technology allows managing patient schedule automatically and displayed in calendar form through the patient management function	Study oversight			1
114	Technology allows managing information about site visit status and results	Operational analytics	Clinical monitoring	Documentation management	1
115	Technology allows managing information related to site-specific SAE	Safety management	Operational analytics	Manage Protocol and GCP deviations	1
116	Technology provides clinical trial management functions related to medical devices from external organizations	Vendor Management	System approval facilitation		1
117	Technology allows managing the clinical drug import and export	Regulatory Management	Study oversight	Documentation management	1
118	Technology allows managing the biomaterial obtained during clinical trials	Vendor Management	Study oversight		1
119	Technology supports SOP management, training and automatic notification by the unit	Inspection facilitation	Documentation management	Study oversight	1
120	Technology provides management functions for tasks to be performed by each user.	Clinical monitoring			0,5
121	Technology allows managing the timeline of study (e.g. regulatory complete)	Study oversight	Regulatory Management	Performance monitoring	0,5

BBB: Close out & Reporting

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
122	Technology enables effective storage, management, and tracking of electronic documents	Archiving			1
123	Technology allows to retrieve, display and re-configure systems parameters and choices made at implementation	Decommissioning			1
124	Technology enables generation of automated medical review summaries based on pre-defined parameters	Producing study report	Publishing of clinical study results	Scientific dissemination of study results	0,5
125	Technology enables generation of automated Clinical study report sections based on pre-defined parameters	Producing study report	Publishing of clinical study results	Scientific dissemination of study results	0,5
126	Technology enables data transfers, archiving, decommissioning of user accounts etc	Decommissioning			1
127	Technology enables creation of CSR appendices from electronic tool (deviations, list of staff (PI and SubI) and others potentially	Archiving			0,5
128	Technology enables tracking and reporting of Close-Out Visits	Study oversight	Operational analytics	Clinical monitoring	1

BBB: Patient engagement

Nr	Criterion	BBB Label (first)	BBB Label (second)	BBB Label (third	Weight
129	Technology provides information about the condition, the trial and the IMP	Educational Engagement	Disease Self-management		0,5
130	Technology enables the patient to start communication and collaboration with provider through the technology platform	Interactive Engagement	Disease Self-management	Safety Monitoring	0,5
131	Technology allows user input and contains prompts (reminders, sharing options, notifications, etc.)	Interactive Engagement	Disease Self-management		1
132	Technology enables that data are available online (almost) immediately	Management of study-generated data	Management of study-generated data	Gathering and management of real-life data	1
133	Technology provides rapid feedback available to patient	Educational Engagement	Disease Self-management	Gathering and management of real-life data	1
134	Technology allows to look at trends in patient engagement	Operational Analytics	Patient Adherance		0,5
135	Technology allows providing acknowledgment or thanks for patient participation.	Interactive Engagement			1
136	Technology is able to provide reminders/alerts about scheduled medication, testing, appointments, activities etc.	Interactive Engagement	Patient Adherance	Disease Self-management	1
137	Technology is able to record/track health information and to display and summarize it for patient	Educational Engagement	Disease Self-management	Patient Adherence	1